REMARKS

Claims 1-25 are now pending in the application. The amendments to the claims contained herein are of equivalent scope as originally filed and, thus, are not a narrowing amendment. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

REJECTION UNDER 35 U.S.C. § 101

Claims 1-7 stand rejected under 35 U.S.C. § 101, because the claimed invention is directed to non-statutory subject matter. Applicant has amended claim 1 to overcome the above-referenced rejection.

Applicant respectfully submits that the claims, as amended, are directed to statutory subject matter. First, Applicant submits that the invention is now tied to a machine, that is a computing device. Second, the invention transforms a particular article to a different state.

Applicant submits that claim 1 requires that the regulatory data be stored "on an electronic regulatory data database residing on the memory of a computing device." Furthermore, claim 1 requires that the first party provide "access to said electronic regulatory data base over a communications network." Thus, the claimed invention cannot be practiced without the invention being tied to a computing device and providing access to the database residing on the computing device to a second party over a communications network. Thus, Applicant respectfully submits that claim 1, as amended, is directed to statutory subject matter.

Additionally, Applicant submits that claim 1 recites steps that transform a

particular article to another state. Claim 1 requires that the first party obtain clinical trial results from clinical trials and to transform said clinical trial results to regulatory data. Furthermore, the clinical trial results are relate to observed physical results of administering the pharmaceutical product to human or animal. In *In re Bilski*, the Federal Circuit noted that the transformation of any physical object or substance, or an electronic signal representative of any physical object or substance constitutes patentable subject matter. 88 U.S.P.Q.2d 1385 (Fed. Cir. 2008). With respect to electronic data, the court stated "[s]o long as the claimed process is limited to a practical application of a fundamental principle to transform specific data, and the claim is limited to a visual depiction that represents specific physical objects or substances, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle." *Id.* In this instance, the regulatory data eventually results from the observed physical results of administering the pharmaceutical product to a human or animal. Thus, the clinical trial results are being transformed to regulatory data, which may be used to obtain regulatory approval to market a pharmaceutical product. Furthermore, as Applicant has limited the claims to the specific application of providing rights to the transformed regulatory data used for obtaining regulatory approval to market a pharmaceutical product, there is no danger that the scope of the claim would wholly pre-empt all uses of the principle.

In view of the foregoing amendments and remarks, Applicant respectfully submits that the claims satisfy both prongs of the machine-or-transformation test as affirmed in *In re Bilski*. 88 U.S.P.Q.2d 1385, 1391 (Fed. Cir. 2008). Accordingly, Applicant requests that the Examiner withdraw the 35 U.S.C. § 101 rejection.

REJECTION UNDER 35 U.S.C. § 112

Claims 1-7 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter which Applicant regards as the invention. This rejection is respectfully traversed.

Applicant has amended claims 1 and 2 to overcome the Examiner's rejections with respect to 35 U.S.C. §112, second paragraph. First, Applicant has removed any instances of the term "secondary" used to modify "market." Second, in claim 1, Applicant has removed the term "utilized" and replaced it with the term "used." Further, Applicant has specified that the data and information can be "used by the second party in a second territory for purposes of obtaining regulatory approval to market the pharmaceutical product in the second territory." Applicant respectfully submits that this amendment should cure any deficiency originally perceived in the claims. Finally, with respect to claim 2, Applicant has removed the ambiguous term "may exceed" and clarified that the amount of compensation "relates to the first party's cost of development." In view of the foregoing amendments, Applicant respectfully requests the Examiner to withdraw the rejections with respect 35 U.S.C. §112.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Nutter, et al. (2003/0061133) in view of PR Newswire (2001). This rejection is respectfully traversed.

Applicant respectfully submits that Nutter fails to teach the limitations of claim 1. Nutter generally relates to a method for funding an intellectual property portfolio. The

party obtaining IP rights ("the seller") will sell the rights to an IP asset investment entity. The investment entity will then license back the IP rights to the seller and provide the right to use the rights and to license the rights. The IP investment entity will then collect royalties from the seller. Thus, in Nutter, an intermediary acts to manage the first party's patent rights. Furthermore, Nutter does not contemplate the first party having rights in regulatory data. Nor does Nutter contemplate the first party conducting clinical trials to obtain the clinical trial results which are transformed into regulatory data. Thus, Nutter cannot be read to teach "a first party having rights in the multinational patent portfolio and the regulatory data providing a territorial distribution of at least some of the rights under said patent portfolio to a second party." (emphasis added). Additionally, Applicant agrees with the Examiner that Nutter fails to disclose "the first party providing access to said electronic regulatory data base over a communications network, said electronic data base representing a market for regulatory data and information, said regulatory data and information relating to the pharmaceutical product subject of the multinational patent portfolio and obtained in the first party's clinical trials and development whereby said data and information can be used by the second party in a second territory for purposes of obtaining regulatory approval to market the pharmaceutical product in the second territory."

It is respectfully submitted that PR Newswire cannot cure the deficiencies of Nutter. More specifically, PR Newswire cannot be read to teach "the first party providing access to said electronic regulatory data base over a communications network, said electronic data base representing a market for regulatory data and information, said regulatory data and information relating to the pharmaceutical product

subject of the multinational patent portfolio and obtained in the first party's clinical trials and development whereby said data and information can be used by the second party in a second territory for purposes of obtaining regulatory approval to market the pharmaceutical product in the second territory." PR Newswire discloses a news story where a first party agreed to grant an exclusive license to a second party to develop a pharmaceutical product. A second agreement entered into by the parties was to establish a "collaborative research and development arrangement under with [the two parties] will jointly research and clinically develop the [new drug]." (emphasis added). The third agreement related to an agreement to jointly engage in enrolling patients in clinical trials. Thus, in PR Newswire, the two parties agreed to cooperate in obtaining the clinical trial results. Conversely, claim 1 recites the first party storing regulatory data on an electronic data base and providing access to the second party over a communications network, so that the regulatory data may be used by the second party to obtain regulatory approval to market the pharmaceutical product in the second territory. This distinction is significant because in PR Newswire, the two parties are engaged in a quasi-partnership, while the two parties in claim 2 are in a seller/buyer relationship. Thus, PR Newswire cannot be used to cure the deficiencies of Nutter. Accordingly, in view of the foregoing arguments and amendments, Applicant respectfully requests that the Examiner withdraw the rejection pursuant to 35 U.S.C. § 103(a).

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: December 23, 2008__

By: /Timothy D. MacIntyre/_____
Timothy D. MacIntyre
Reg. No. 42,824

HARNESS, DICKEY & PIERCE, P.L.C.
P.O. Box 828
Bloomfield Hills, Michigan 48303
(248) 641-1600

TDM/TSE/med